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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/18/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/403,262

Applicant(s)

THERES, NIKOLAUS

Examiner

Ashwin Mehta

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 23-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 26 March 2002 is: a) ☐ approved b) ☒ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to the specification for failing to comply with 37 CFR 1.821-1.825 is withdrawn in light of the insertion of the sequence identifiers in the brief description of drawings.
3. The objections to claims 1-3 and 5-22 are moot, in light of their cancellation.
4. The rejection of claims 1-3 under 35 U.S.C. 101 is moot, in light of their cancellation.
5. The rejections of claims 2 and 10-20 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph under items 7-10 in the Office action mailed 13 September 2001 is moot, in light of their cancellation.
6. The rejections of claims 1, 2, 5-13, and 15-22 under 35 U.S.C. 102 and/or 103(a) are withdrawn, in light of their cancellation and because of the difference in scope of the new claims.

### ***Drawings***

7. Corrected or substitute drawings were received on 26 March 2002. These drawings are accepted for examination. However, see the accompanying Form PTO-948.

Art Unit: 1638

8. The following information on effecting drawing changes replaces the information that appears on the back of the accompanying Form PTO-948.

**Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

**Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

***Claim Objections***

9. New claims 27-29, 31, 32, 40, and 41 are objected to.

In line 1 of claims 27 and 28, line 3 of claim 32: the "a" "a nucleic acid molecule" should be --the--.

In line 1 of claims 29 and 31: "A" should be --The--.

In claims 40 and 41, "a" should be --the--.

***Claim Rejections - 35 USC § 112***

10. New claims 23 and 25-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed 13 September 2001 on page 4 under item 6 for claims 1 and 5-22. Applicants traverse the rejection in the paper received 26 March 2002.

Applicant's arguments have been fully considered as they apply to new claims 23 and 25-42 but were not found persuasive. Applicants argue that the term "derivative" appears multiple times in the specification and is defined on page 21 as including sequences derived from SEQ ID NO: 1 by insertion, deletion, or substitution (response, paragraph bridging pages 6-7). However, any sequence can be derived by insertion, deletion, or substitution of nucleotides in SEQ ID NO: 1. The definition on page 21 also does not distinguish derivatives from fragments. Further, the definition only refers to a subset of the derivatives. It is not clear what the derivatives are that do not include sequences derived from SEQ ID NO: 1 by insertion, deletion, or substitution. The metes and bounds of the claims are therefore unclear.

11. Claims 23-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1638

In claim 23: the recitation “a polypeptide having the biological activity of side-shoot formation, petal formation, and abscission zone formation” in lines 4-5 and 7-8, and 11-12 renders the claim indefinite. It is not clear what is meant by “biological activity of side-shoot formation, petal formation, and abscission zone formation.” The recitation does not make clear what the biological activity of the polypeptide actually is.

Further in claim 23: parts (a) and (c) of the claim renders the claim indefinite. Part (a) indicates that both the nucleic acid having the nucleotide sequence of SEQ ID NO: 1 and its complement encode the same polypeptide. Part (c) renders the claim indefinite for the same reason, excepting that it indicates that nucleic acids that hybridize with SEQ ID NO: 1 or its complement, encode the same polypeptide.

Further in claim 23: the recitation “a nucleic acid that hybridizes with said nucleic acid” in line 9 is confusing. It is suggested that the first recitation of “nucleic acid” in line 9 of claim 23 be replaced with --nucleic acid sequence--.

In claim 24: the recitation “high stringency conditions” in line 2 renders the claim indefinite. High stringency conditions are not defined in the specification.

In claim 32: the term “modified” in lines 1 and 5 renders the claim indefinite. It is not exactly clear what is encompassed by the term. Is the timing of side-shoot, petal, and abscission zone formation modified, are these structures shaped differently, do these structures form in different locations on the plant, etc.?

In claims 35-37: the recitation “wherein the integrating step further comprises integrating” in line 1 of the claims render them indefinite. It is not clear if the term “further” is supposed to imply that another integration step takes place in addition to the integration step of parent claim 32. If only one integration step is intended, then it is suggested that the term “further” be deleted from claims 35-37.

12. New claims 23-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 13 September 2001 under item 11 for claims 1, 2, and 5-22.

Applicants traverse the rejection in the paper received 26 March 2002. Applicants argue that the new claims indicate that the hybridizing nucleic acids have the biological activity of side-shoot, petal, and abscission zone formation (response, paragraph bridging pages 7-8). Applicants argue that the specification describes complementation experiments using subfragments of cosmid G, and that subsequence DNA analysis was conducted to determine that particular base deletions, insertions, or point mutations contribute to an altered phenotypic appearance (response, page 8, second full paragraph).

Applicant’s arguments have been fully considered as they apply to new claims 23-42, but were not found persuasive. The claims encompass nucleic acids having nucleotide sequences that are not structurally related to SEQ ID NO: 1. The claims encompass derivatives of SEQ ID NO: 1, which include nucleotide sequences that can differ from SEQ ID NO: 1 by any deletion,

Art Unit: 1638

substitution, or addition. This yields nucleotide sequences that have no structural relation to SEQ ID NO: 1. The claims also encompass nucleic acids that hybridize to SEQ ID NO: 1 or its complement. However, the stringency conditions for the hybridization are not defined.

Therefore any and all nucleic acids are encompassed by the claims, as any two nucleic acid sequences would hybridize to some extent given the appropriate hybridization conditions. Claim 23 indicates that the hybridizing nucleic acid encodes a polypeptide having the biological activity of side-shoot, petal, and abscission zone formation. However, these hybridizing nucleic acids encompass structures that have no relation to SEQ ID NO: 1, which encodes SEQ ID NO: 2. The only structure that is described by the specification as having the function of promoting side-shoot, petal, and abscission zone formation, in non-transgenic tomato plants, are the nucleotide sequences that encode SEQ ID NO: 2. All of the subfragments of cosmid G that were used in the complementation experiments still comprised the full coding region for SEQ ID NO: 2. Further, none of the base deletions, insertions, or point mutations described in the specification, including those referred to by Applicant in the response, encoded a protein that retained the activity of SEQ ID NO: 2. Claim 24 is included in this rejection because the high stringency conditions are not defined, and therefore the descriptions of all of the nucleic acid molecules encompassed by the claim are unknown.

13. Claims 23-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the



Art Unit: 1638

invention, for the reasons of record stated in the Office action mailed 13 September 2001 under item 12 for claims 1, 2, and 5-22.

Applicants traverse the rejection in the paper received 26 March 2002. Applicants argue that the Ls cDNA constructs can be used to transform, e.g., a plant to observe any phenotypic modification (response, paragraph bridging pages 9-10). Applicants argue that because the specification teaches the Ls gene is involved in side-shoot, petal, and abscission zone formation, and how to prepare and isolate Ls clones containing SEQ ID NO: 1 for subsequent transformation, that one can ascertain the resulting plant phenotype (response, page 10, first full paragraph). Applicants also argue that making of the claimed fragments and derivatives is routine (response, page 10, third full paragraph).

Applicant's arguments have been fully considered as they apply to new claims 23-42, but were not found persuasive. Applicant's response indicates that the phenotype of transgenic plants overexpressing the claimed nucleic acids is unknown. The specification cannot enable one skilled in the art to use a plant when the phenotype of that plant is not taught. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. Further, as discussed above, the only fragments and substitutions, additions, and/or insertions to SEQ ID NO: 1 that are taught by the specification are those which do not retain the activity of SEQ ID NO: 1. Applicants argue that preparation of fragments and derivatives is routine, but the only fragments of SEQ ID NO: 1 or changes made to SEQ ID NO: 1 as taught in the specification yielded nucleic acid sequences in which the activity encoded by SEQ ID NO: 1 was abolished. The specification does not provide any guidance concerning how

Art Unit: 1638

to prepare the claimed fragments and derivatives which encode amino acid sequences that retain the activity of SEQ ID NO: 2. In the absence of this guidance, the experimentation required by one skilled in the art to make the fragments and derivatives is undue.

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

#### ***Contact Information***

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M.

Art Unit: 1638

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A.M.  
June 12, 2002

A handwritten signature in cursive script, reading "Amy Nelson".

**AMY J. NELSON, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600**